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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,963	08/26/2005	Peter H Seeberger	MTV-055.01	4931
25181	7590	05/14/2008		
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			EXAMINER HENRY, MICHAEL C	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 05/14/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,963	<b>Applicant(s)</b> SEEBERGER ET AL.	
	<b>Examiner</b> MICHAEL C. HENRY	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-11 and 13-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 and 27-30 is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11 is/are rejected.
- 7) ☒ Claim(s) 13-26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/10/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/22/08.

The amendment filed 01/22/08 affects the application, 10/520,963 as follows:

1. Claims 10, 17-19, 27, 30 have been amended.
2. The responsive to applicants' amendments is contained herein below.

Claims 1, 3-11, 13-30 are pending in application.

#### *Claim Objections*

Claims 1 and 19 are objected to because of the following informalities: The claims the phrase or symbols " $\text{Li}^+$ ,  $\text{Li}^{++}$ " which appears to be a typographical error. It appears that one of the  $\text{Li}^+$  should be deleted from the phrase. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 102*

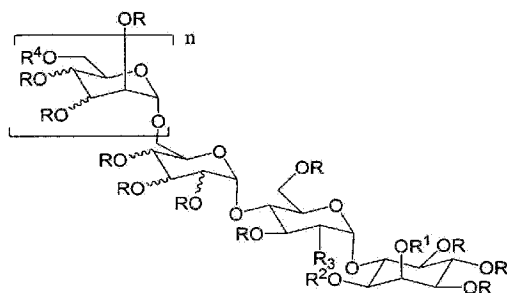
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaworek et al. (Carbohydrates Research 331 (2001) 375-391).

In claim 1, applicant claims a compound represented by formula I:



wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)<sub>3</sub>;

R<sup>1</sup> and R<sup>2</sup> are independently H, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>; or R<sup>1</sup> and R<sup>2</sup> taken together are C(CH<sub>3</sub>)<sub>2</sub>, P(O)OH, or P(O)OR<sup>5</sup>;

R<sup>3</sup> is amino, -N<sub>3</sub>, or -NH<sub>3</sub>X;

R<sup>4</sup> represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>, or -P(O)(OR<sup>5</sup>)<sub>2</sub>;

R<sup>5</sup> represents independently for each occurrence H, Li<sup>+</sup>, Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, Rb<sup>+</sup>, Cs<sup>+</sup>, aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

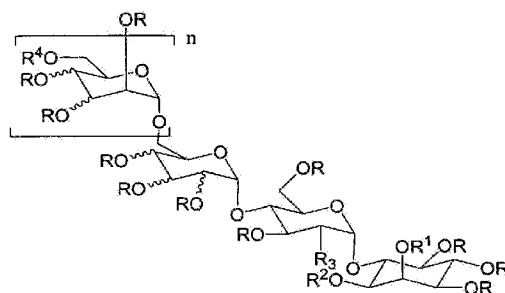
Jaworek et al. disclose applicant's compound of formula I wherein n = 1; R = H; R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH; R<sup>3</sup> = amino; R<sup>4</sup> = H (see compound 3, page 376). It should be noted that although compound 3 is represented with R<sup>3</sup> = NH<sub>3</sub><sup>+</sup> and R<sup>1</sup> and R<sup>2</sup> taken together = P(O)O<sup>-</sup> this compound is the same as applicant's compound wherein R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH and R<sup>3</sup> = amino (i.e., -NH<sub>2</sub>) since at a given pH (probably in pure water) the O<sup>-</sup> on the P(O)O<sup>-</sup> group will be protonated to give P(O)OH and NH<sub>3</sub><sup>+</sup> will be deprotonated to give the amino (i.e., -NH<sub>2</sub>). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claim 4 which is drawn to the compound of claim 1, wherein

Art Unit: 1623

R is H, is also anticipated by Jaworek et al., since in Jaworek et al.'s compound R is H (see compound 3, page 376). Claim 5 which is drawn to the compound of claim 1, wherein  $R^1$  and  $R^2$  taken together is  $P(O)OR^5$ , is also anticipated by Jaworek et al., wherein  $R^5$  (see compound 3, page 376). It should be noted that although compound 3 is represented with  $R^3 = NH_3^+$  and  $R^1$  and  $R^2$  taken together =  $P(O)O^-$  this compound is the same as applicant's compound wherein  $R^1$  and  $R^2$  taken together is  $P(O)OH$  and  $R^3 = \text{amino}$  (i.e.,  $-NH_2$ ) since at a given pH (probably in pure water) the  $O^-$  on the  $P(O)O^-$  group will be protonated to give  $P(O)OH$  and  $NH_3^+$  will be deprotonated to give the amino (i.e.,  $-NH_2$ ). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claims 8 and 9 which are drawn to the compound of claim 1, wherein  $R^4 = H$  ..., is also anticipated by Jaworek et al., since  $R^4 = H$ , for Jaworek et al.'s compound (see compound 3, page 376). Claim 6 which is drawn to the compound of claim 1, wherein  $R^3 = N_3$ , is anticipated by Jaworek et al. (see compound 30b, page 380). It should be noted that in Jaworek et al.'s compound 30b, n is 1 and independently  $R = -CH_2\text{-aryl} = -CH_2\text{-phenyl} = \text{Bn}$ , where Bn = benzyl and  $R = H$  (see compound 30b, page 380).

Claims 1, 3-5, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin-Lomas et al. (Chem. Eur. J. 2000, 6, No. 19, pages 3608-3621).

In claim 1, applicant claims a compound represented by formula I:



I

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)<sub>3</sub>;

R<sup>1</sup> and R<sup>2</sup> are independently H, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>; or R<sup>1</sup> and R<sup>2</sup> taken together are C(CH<sub>3</sub>)<sub>2</sub>, P(O)OH, or P(O)OR<sup>5</sup>;

R<sup>3</sup> is amino, -N<sub>3</sub>, or -NH<sub>3</sub>X;

R<sup>4</sup> represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>, or -P(O)(OR<sup>5</sup>)<sub>2</sub>;

R<sup>5</sup> represents independently for each occurrence H, Li<sup>+</sup>, Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, Rb<sup>+</sup>, Cs<sup>+</sup>, aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

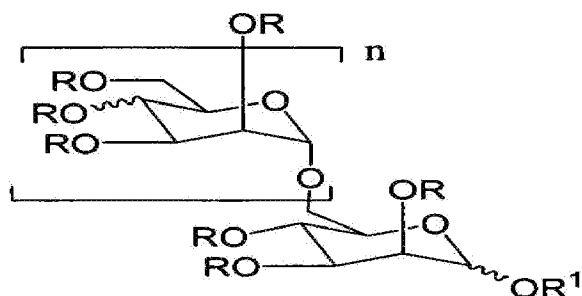
Martin-Lomas et al. disclose applicant's compound of formula I wherein n = 3; R = H; R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH; R<sup>3</sup> = amino; R<sup>4</sup> = H (see compound 2, page 3609). It should be noted that although compound 2 is represented with R<sup>3</sup> = NH<sub>3</sub><sup>+</sup> and R<sup>1</sup> and R<sup>2</sup> taken together = P(O)O<sup>-</sup> this compound is the same as applicant's compound wherein R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH and R<sup>3</sup> = amino (i.e., -NH<sub>2</sub>) since at a given pH (probably in pure water) the O<sup>-</sup> on the P(O)O<sup>-</sup> group will be protonated to give P(O)OH and NH<sub>3</sub><sup>+</sup> will be deprotonated to give the amino (i.e., -NH<sub>2</sub>). That is, Martin-Lomas et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claim 3 which is drawn to the compound of

Art Unit: 1623

claim 1, wherein n is 3, is also anticipated by Martin-Lomas et al., since in Martin-Lomas et al.'s compound n is 3 (see compound 2, page 3609). Claim 4 which is drawn to the compound of claim 1, wherein R is H, is also anticipated by Martin-Lomas et al., since in Martin-Lomas et al.'s compound R is H (see compound 2, page 3609). Claim 5 which is drawn to the compound of claim 1, wherein  $R^1$  and  $R^2$  taken together is  $P(O)OR^5$ , is also anticipated by Martin-Lomas et al., wherein  $R^5$  (see compound 2, page 3609). It should be noted that although compound 2 is represented with  $R^3 = NH_3^+$  and  $R^1$  and  $R^2$  taken together =  $P(O)O^-$  this compound is the same as applicant's compound wherein  $R^1$  and  $R^2$  taken together is  $P(O)OH$  and  $R^3 = \text{amino}$  (i.e.,  $-NH_2$ ) since at a given pH (probably in pure water) the  $O^-$  on the  $P(O)O^-$  group will be protonated to give  $P(O)OH$  and  $NH_3^+$  will be deprotonated to give the amino (i.e.,  $-NH_2$ ). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claims 8 and 9 which are drawn to the compound of claim 1, wherein  $R^4 = H$  ..., is also anticipated by Martin-Lomas et al, since  $R^4 = H$ , for Martin-Lomas et al.'s compound (see compound 2, page 3609).

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Kong et al. (CN 1297892) (Abstract Only).

In claim 11, applicant claims "A compound represented by formula II:



**II**

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)<sub>3</sub>;

R<sup>1</sup> is -(CH<sub>2</sub>)<sub>m</sub>CH=CH<sub>2</sub> or trichloroacetimidate; and

m is 1-6.

Kong et al. disclose applicant's compound of formula II wherein n = 1; R = -C(O)-aryl = -C(O)-phenyl, and R = -C(O)-alkyl = -C(O)-methyl, and R<sup>1</sup> = trichloroacetimidate (trichloroethanimidate).

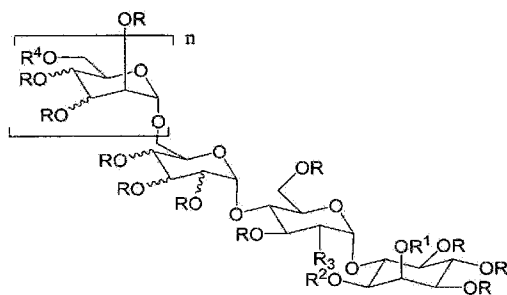
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jaworek et al. (Carbohydrates Research 331 (2001) 375-391).

In claim 1, applicant claims a compound represented by formula I:





wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)<sub>3</sub>;

R<sup>1</sup> and R<sup>2</sup> are independently H, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>; or R<sup>1</sup> and R<sup>2</sup> taken together are C(CH<sub>3</sub>)<sub>2</sub>, P(O)OH, or P(O)OR<sup>5</sup>;

R<sup>3</sup> is amino, -N<sub>3</sub>, or -NH<sub>3</sub>X;

R<sup>4</sup> represents independently for each occurrence H, alkyl, aryl, -CH<sub>2</sub>-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)<sub>3</sub>, or -P(O)(OR<sup>5</sup>)<sub>2</sub>;

R<sup>5</sup> represents independently for each occurrence H, Li<sup>+</sup>, Li<sup>+</sup>, Na<sup>+</sup>, K<sup>+</sup>, Rb<sup>+</sup>, Cs<sup>+</sup>, aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

Claim 7 is drawn to a compound of claim 1, wherein R<sup>3</sup> = -NH<sub>3</sub>X.

Jaworek et al. disclose applicant's compound of formula I wherein n = 1; R = H; R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH; R<sup>3</sup> = amino; R<sup>4</sup> = H (see compound 3, page 376). It should be noted that although compound 3 is represented with R<sup>3</sup> = NH<sub>3</sub><sup>+</sup> and R<sup>1</sup> and R<sup>2</sup> taken together = P(O)O<sup>-</sup> this compound is the same as applicant's compound wherein R<sup>1</sup> and R<sup>2</sup> taken together is P(O)OH and R<sup>3</sup> = amino (i.e., -NH<sub>2</sub>) since at a given pH (probably in pure water) the O<sup>-</sup> on the P(O)O<sup>-</sup> group will be protonated to give P(O)OH and NH<sub>3</sub><sup>+</sup> will be deprotonated to give the amino (i.e., -

Art Unit: 1623

NH<sub>2</sub>). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form.

The difference between applicant's claimed compound and the compound taught by Jaworek et al. is that the applicant's compound is the ammonium halide salt (e.g., when X = Cl<sup>-</sup>) of Jaworek et al.'s compound. However it is common in the art to prepare the salt form of a drug such as the ammonium halide salt of Jaworek et al.'s compound with the expectation that the salt form would have the same or even better pharmaceutical effect.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Jaworek et al., to have prepared a salt form of Jaworek et al.'s compound such as the ammonium halide salt, in order to use it to treat conditions such as malaria or diabetes since a skilled artisan would expect or predict that the salt form of Jaworek et al., compound would have the same or even better pharmaceutical or medicinal effect.

One having ordinary skill in the art would have been motivated to prepare a salt form of Jaworek et al.'s compound such as the ammonium halide salt, in order to use it to treat conditions such as malaria or diabetes based on factors such as availability and cost, since a skilled artisan would expect or predict that the salt form of Jaworek et al., compound would have the same or even better effect on said diseases or conditions.

*Allowable subject matter*

Though the compounds of the present invention are similar to the compounds of the prior art, the compounds of claim 10 possess structural differences to the compounds of prior art documents and these differences are not suggested in the prior art, nor are obvious over the prior

Art Unit: 1623

art. For example, the compounds of claim 10 contain different numbers of monosaccharide residues and different types of functional groups or moieties attached to their pyranose rings as compared to the compounds of the prior art. Similarly, Claims 13-18 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 19-26 are objected to as set forth above, but may be allowable provided that said objections are overcome, since the prior art does not teach or suggest the method recited in said claims. Also, the prior art does not teach or suggest the method recited in Claims 27-30.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-9, 11 have been considered but are not found convincing.

The applicant argues that Solely to expedite the prosecution of this application, the Applicants have amended independent claim 1 so that  $R^4$  can not be H; and further amended independent claim 11 so that n can not be 1. As the compounds cited by the Examiner do not fall within the scope of the amended claims, the cited art is thus not anticipatory. Therefore, the Applicants respectfully request the Examiner withdraw his rejections of claim 1, 3-6, 8, 9 and 11 under 35 USC § 102(b) based on Jaworek, Martin-Lomas, and Kong. However, applicant's claims presently or instantly recite that  $R^4$  can be H (see claims). Consequently, applicant's amendment has not overcome the rejections based on Jaworek, Martin-Lomas, and Kong. It should be noted that the reference to Rademacher *et al.* (WO 01/85745 A1) which was inadvertently inserted, copied or pasted in the previous action is presently withdrawn. Also, it

Art Unit: 1623

should be noted that claim 3, which was mistakenly indicated as been allowable although it was rejected in the previous office action, is not allowable.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

May 10, 2008.

/Shaojia Anna Jiang, Ph.D./  
Supervisory Patent Examiner, Art Unit 1623